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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,370

Applicant(s)

MAILLIET ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,18-26,28,29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,18-26,28,29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Applicants' response, which included cancellation of claims 16,17, 27, 30, addition of new claims 32-35 and amendment to claims 1, 5-15, 18-25 and 31, filed on 11/14/2003, is made of record.

Claims 1-2, 4-15, 18-26, 28-29, and 31-35 are now pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

In view of applicants' response, all 112 second paragraph rejections made in the previous office action have been obviated. However, the following rejections made in the previous office action remain.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 4-15,18-26, 28-29, and 31-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "thiol" and "hydroxy" or amino radical as substituents in the triazine, does not reasonably provide enablement for thio radical substituted with halogen, oxy radical substituted with halogen or amino radical substituted with halogen as recited for compound of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the invention commensurate in scope with these claims. Note dependent claims 2, and 4-15,18-26, 28-29, and 31-35 are also rejected herein as they depend on the rejected claim 1.

In evaluating the enablement question, following factors are considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include:

1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1. The nature of the invention and the state of the prior art:

The invention is drawn to compound of formula shown in claim 1 wherein the distribution group is triazine. Claim permits halogen substituents on "thio" or "oxy" or "amino" radical in presence of similar reactive groups on the quinoline or benzamidine or nonaromatic hydrocarbon chain. Specification is not adequately enabled as to how to make compounds of formula shown in claim 1 wherein the above said groups are variously substituted with reactive functional groups such as HO, NH₂, amidine and thiol groups which are also susceptible to halogenation.

Specification offers no teachings or suggestion as to how to perform the halogenation and make such compounds in presence of these reactive groups.

2. The predictability or lack thereof in the art:

The process of halogenation as applied to the above-mentioned compounds claimed by the applicant is not an art-recognized process and hence there should be adequate enabling disclosure in the specification with working example(s) to make these claimed compounds.

4. The amount of direction or guidance present:

Examples illustrated in the experimental section or written description offer no guidance or teachings as to how make these compounds when reactive substituents or chemically incompatible substituents are present in the starting material.

5. The presence or absence of working examples:

Although examples on pages 28-37 show enablement for number of compounds, they are limited to compounds with no reactive functionality. There are no representative examples showing the viability of the process for the reactive thiohalo, oxyhalo, or aminohalo substituents embraced in the instant claims.

6. The breadth of the claims:

Specification has no support, as noted above, for all compounds generically embraced in the claim language would lead to desired compound of formula I with said reactive groups and there is also no valid chemical reasoning for one trained in the art to expect that all these functional groups would be inert toward the reaction to make such thiohalo, oxyhalo, or aminohalo compounds.

7. The quantity of experimentation needed:

The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of experimentation, there is no guarantee that one would get the product of desired structure, namely compound of formula shown in claim 1 in view of the general reactive of thiohalo, oxyhalo, or aminohalo groups.

Thus, factors such as "sufficient working examples", the "level of skill in the art and predictability, etc. have been demonstrated to be sufficiently lacking in the case for the instant claims.

Applicants' should note that this rejection is same as made in the previous office action except that cancelled claims are excluded and newly added claims are included in this rejection.

Applicants' traversal to overcome this rejection is not persuasive.

First of all the issue is whether one can make S-halogen, O-halogen or N-halogen compounds. The issue is can such compounds be made in presence of equally reactive groups. Specification does not provide any teaching or suggestion as to how to make these compounds in presence of reactive groups and it is known such positive halogen groups are reactive groups.

Secondly, there are no prior art teaching such a class of compounds can be made in presence of reactive groups. Examiner had clearly indicated that he had indeed searched the literature.

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Therefore, it is applicants burden to show that such a class of compounds can be made in presence of reactive groups and share the same use.

Hence this rejection is deemed as proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-9, 11-15, 18-26, 28-29, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daeyaert et al US 6,150,360 for reasons of record.

To repeat:

1. Determining the scope and contents of the prior art.

Daeyaert et al. teaches several trisubstituted triazines, which include generically compounds of claimed in the instant claims, for the treatment of HIV infection. See formula I on col. 1, lines 30-40 and note the definition of L, A, R¹, R², R³ and R⁴ and n. Note with these definitions, compounds taught by Daeyaert et al. corresponds to instant triazine with pyridine as nitrogen containing aromatic ring and L as nonaromatic hydrocarbon chain groups. See col. 2 through 9 for preferred embodiments and examples of the compounds on col. 9-10, process of making and compounds made on col. 10 through col. 22. See col. 23 to 27 for compounds made, especially see Table 2 and Table 3.

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims differ from the reference in reciting specific substituent pyridine in the triazine ring.

3. Resolving the level of ordinary skill in the pertinent art.

However Daeyaert et al. teaches the equivalency exemplified examples of trisubstituted core, shown on col. 9 and Table 2 and Table 3 with those claimed therein in the definition of various variable groups of formula I on col. 1. See definition of L, A, R¹, R², R³ and R⁴ and n shown on col. 1-2 and preferred embodiments of these groups on col. 2-9.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted the triazine ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness

The application does not offer any unexpected /superior results or any objective evidence that would suggest the instant invention is not an obvious variant.

Applicants' should note that this rejection is same as made in the previous office action except that cancelled claims 16, 17, 27 are excluded and newly added claim 34 are included in this rejection.

Applicants' traversal to overcome this rejection is not persuasive.

Contrary to applicants' urging, citing *In re Vaeck*, 947 F2d 488, 20, USPQ 2d 1438 (Fed. Cir 1991), there is motivation for one trained in the art to make and use the compounds taught by Daeyaert et al. for treating HIV infection. Daeyaert et al. clearly teaches that the triazine compounds are useful for treating HIV and one trained in the art would be motivated to make use of the teachings of Daeyaert et al. as he would expect the genus as whole would have desired use taught in the reference.

As for *In re Dembiczak* 175 F.3d 994, 999, 50 USPQ 2d 1614 (Fed. Cir 1999) cited, applicants should note that there is no modification needed as Daeyaert et al clearly teaches a genus and 87 specific compounds along with equivalency of exemplified species with those embraced in the genus. Thus one trained in the art

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would be able to make any compound embraced in the genus and one would expect it to be active against HIV based on the teachings of Daeyaert et al.

Again contrary to applicants' urging citing *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992) and *In re Lalu*, 747 F.2d 703, 705 223 USPQ 1257, 1258 (Fed. Cir. 184), there is objective teaching in Daeyaert et al. To restate, Daeyaert et al teaches a genus of triazine compounds along with specific species useful for treating HIV infection. This is clearly an objective teaching and there is nothing in the above rejection drawn from instant invention. The fact that 87 compounds of the genus are made and tested is would be enough for one trained in the art to make and use the teachings of Daeyaert et al.

The desirability of the compounds of the genus of Daeyaert et al. for treating HIV infection would also negate applicants' argument citing *In re Mills* 916 F.2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990).

As for applicants' traversal indicating, "not only what it expressly teaches, but also what it fairly suggests", Daeyaert et al. teaches a genus of triazine compounds useful for treating HIV infection, exemplifies 87 compounds of the genus and fairly suggests that rest of the compounds can be made with given teaching and they would share the same utility. Thus both the expressed teaching and fair suggestion criteria required are met within Daeyaert et al.

As for applicants' reliance on *In re Baird*, 16 F. 3d 380, 382, (Fed. Cir. 1994), unlike *In re Baird*, in Daeyaert et al., there is clear-cut guidance for selecting substituents for the triazine core based on the exemplified compounds and therefore

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one trained in the art would be able to arrive at substituted triazine compounds. In addition, In re Baird is not applicable as there is a clear-cut equivalency teaching in Daeyaert et al. Thus there is guidance for making the triazine compounds with any desired substituents. Furthermore, applicants have not shown that what substituents is not taught or suggested that cannot be arrived at from the teachings of Daeyaert et al.

Finally, applicants' argument that there is no equivalency teaching in Daeyaert et al. based on the physical differences is not tenable argument. Equivalency teaching is not based on such differences. There are based on what substituents and core groups if attached to the core triazine would lead to compounds with the same utility. Daeyaert et al. in the generic structure and species exemplified clearly teaches those groups that would lead to the desired activity against HIV infection.

Hence this rejection is deemed as proper and is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

02/08/2004